EXHIBIT 66

¶ 34,157 MEDICAID—LIMITATION ON PAYMENT FOR DRUGS

Medicaid Action Transmittal, No. 84-12, Sept. 1984. Subject: "Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs."

Medicaid—Limitation on payment for drugs.—Reproduced in this *Action Transmittal* is a Report of the HHS Office of Inspector General explaining how states can save money under Medicaid by paying for drugs at rates paid by pharmacies, rather than paying the average wholesale price as is often the custom. The Report also recommends revision of federal Medicaid regulations to provide better economy in drug reimbursement. *Back reference:* ¶ 14,723.29.

INTRODUCTION

BACKGROUND

Medicaid -- authorized by Title XIX of the Social Security Act -- is a grant-in-aid program under which the Federal Government is currently paying from 50 to 78 percent of the costs incurred by states in providing medical services to persons unable to pay for such care. Certain medical services are required to be provided by the Act while others, such as prescription drugs, may be included in the program if a state so chooses. All 50 states now have a Medicaid program, and all except two states have elected to cover prescribed drugs. The Medicaid program is administered at the Federal level by the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS).

Under the present Federal regulations covering Medicaid reimbursement for drugs (42 CFR 447.331-.334), the State Medicaid agencies may not pay more for prescribed drugs than the lower of ingredient cost plus a reasonable dispensing fee or the provider's usual and customary charge to the general public.

The ingredient cost of a prescription drug is defined as the lower of (1) the maximum allowable cost (MAC) as established by the HHS Pharmaceutical Reimbursement Board for certain multiple-source drugs or (2) the estimated acquisition cost (EAC) of the drug. The MAC provision which was designed to take advantage of the price differentials between brand name drugs and lower-priced generic equivalents, limits ingredient cost reimbursement to the less expensive generic equivalent price.

Specifically, the regulations state that EAC means the State Medicaid agency's "best estimate of what price providers generally are paying for a drug." The regulations further state that "the basis for the estimate must be the package size providers buy most frequently." EAC reimbursement limits must be established for all drugs, both single and multiple-source (even if the drug has a MAC).

HCFA has allowed the states considerable latitude in the design and administration of their Medicaid drug program; particularly in the development and use of their EAC limits. Currently, State Medicaid agencies utilize various methodologies in determining EAC. The most commonly used method is based on published average wholesale prices (AWP). Some states, however, along with AWP use direct manufacturer's prices, state established MAC prices, and other methods to contain costs for certain drugs.

For the year ended December 31, 1982, the prescription drug program expenditures amounted to about $1.7 billion nationwide (Federal share about $900 million).

SCOPE OF AUDIT

Our review was made in accordance with generally accepted governmental auditing standards pertaining to economy and efficiency audits. The primary objective of our review was to determine the effectiveness of HCFA's present EAC requirements in limiting reimbursement for prescription drugs to reasonable levels.

Audit effort was performed in two phases. During the first phase, we performed a detailed review related to the economy and efficiency of the EAC program in the State of Arkansas. In addition, we gathered data from State Medicaid agencies regarding prescription drug reimbursements in 45 other states and the District of Columbia (hereinafter referred to as a State or State Medicaid agency). During the second phase of our review, we performed additional fieldwork in five other states -- Massachusetts, North Carolina, Michigan, Colorado and Oregon. These states were selected primarily based on their geographical location.

Our fieldwork under the first phase of the review included work at the Arkansas Department of Human Services, as well as an examination of 2,086 purchase invoices for 38 sampled drugs at 60 pharmacies scattered throughout the State. In selecting the pharmacies, we considered (1) the amount of Medicaid payments received, (2) whether they were part of chains or independently owned, (3) their geographic location within the state, and (4) the size of the town in which they were located (covering both small and large). With regard to the drugs selected, our analysis showed that 345 drugs accounted for about 75 percent of the dollar volume of the Arkansas drug program. Out of those 345, we selected 38 drugs for our sample. Subsequently, however, one of our selected drugs was recalled by the manufacturer and another was put on the Department's list of ineffective drugs. As a result, we reduced our sample to 36 drugs for our fieldwork in the additional states.

During the second phase of our review, fieldwork was performed at State Medicaid agencies and 48 provider pharmacies in five additional states (Massachusetts - 9, North Carolina - 10, Michigan - 9, Colorado - 10, and Oregon - 10). The criteria for selecting the providers in these states was generally the same as used in Arkansas. At the additional State Medicaid agencies, we determined the procedures for establishing EAC, as well as the EAC for each of the 36 sample drugs. At the pharmacies, we obtained the prices actually paid for each of the 36 drugs purchased in order to determine whether the variances between actual prices paid by providers and AWP, found in Arkansas, were prevalent on a nationwide basis.

OVERVIEW OF THE PROBLEM AND IMPROVEMENTS NEEDED

Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program. The purpose of this report is to alert Departmental management officials to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of average wholesale prices (AWP) in determining program reimbursement for prescription drugs. Currently, most states use AWP as the upper reimbursement limit for drugs -- approximately 80 percent, or about $1.3 billion, of the total annual Medicaid drug expenditures ($1.7 billion) are reimbursed with AWP serving as the upper reimbursement limit.

Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price. Because of the widespread use of AWP by State Medicaid agencies, however, the Medicaid program does not receive any benefit from these discounts. We estimate that as much as $128 million ($72 million Federal share) could be saved annually through changes in program policy and regulations which would restrict the use of AWP as an upper limit in drug reimbursements. We believe that Federal savings over the next five years could amount to at least $360 million.

The need for cost containment action by HCFA seems particularly appropriate at the current time. In June 1983, the Secretary established a special Task Force to review the reimbursement methods used for prescription drugs purchased under Federally-assisted health care programs. We believe that the issues discussed in this report and the recommendations made will be of value to the Task Force.

The use of AWP in determining Medicaid reimbursement for drugs has been a problem that HCFA has recognized for some time. However, efforts to date to control the problem have not been successful. HCFA has periodically supplied State Medicaid agencies with invoice price level data designed to assist them in evaluating their Estimated Acquisition Cost (EAC) limits. However, the data supplied has not been an adequate substitute for AWP and may have been counterproductive since the amounts furnished have often been very similar to the AWP for individual drugs. The statistics gathered by HCFA are based on drug prices shown on invoices. These prices are generally list prices and do not reflect any purchase or trade discounts received when payments are made by the pharmacies.

HCFA believed that published AWP was too high and, therefore, the purpose of the EAC requirement in the regulations was to move states away from using AWP as the upper limit for reimbursing drug ingredient cost. However, the states have been allowed a great deal of latitude in establishing their EAC programs, and most states continue to use AWP as their upper reimbursement limit. Our fieldwork in the six states and inquiries in 41 additional states disclosed that 27 states primarily use AWP in establishing their reimbursement limits. The remaining 20 states use AWP to a great extent, but also use other techniques in establishing their EAC which result in lower reimbursement limits for certain drugs.

Our review in the six states showed that pharmacies rarely purchased the sample drugs at the published AWP. In fact, of the 3,469 drug purchases that we examined, only 14 purchases (.4 percent) were made at AWP or greater. (These 14 purchases were generally made only because of extenuating circumstances, such as special fill-in orders where discounts were not given because only one item was purchased.) Most of the purchases -- 3,455 (99.6 percent) -- were made at prices averaging about 16 percent below AWP. These drug purchases ranged from as little as .23 percent below AWP to as much as 42 percent below AWP.

We found that neither the location nor size of the towns in which the pharmacies were located, nor the types of ownership, affected the availability of the discounts. Purchase discounts were available and were taken by pharmacies in all areas of the selected states, regardless of population, by both chain-owned and independently-owned pharmacies.

Although we found that drug purchases were made at prices averaging about 16 percent below AWP, it must be recognized that drug sales are competitive and many pharmacies bill the Medicaid program for less than AWP (for drug ingredient cost) plus the designated dispensing fee. Thus, the provider

pharmacy's usual and customary charge (UCC) to the general public is an important limiting factor and must be considered when quantifying the effect of State Medicaid agencies using AWP in their drug pricing files. After considering the effect of UCC on payments for our sample drugs, we estimate that about 11 percent of the Medicaid drug reimbursement is in excess of cost plus dispensing fees in those states using AWP as an upper limit for reimbursement.

Of the estimated $1.3 billion that was reimbursed using AWP, approximately $735 million was paid in 27 states using AWP almost exclusively in establishing their EAC. We believe that about 11 percent, or $81 million of these expenditures were unnecessary. The remaining 20 states had expenditures of about $590 million based on AWP; however, these states had already avoided sizeable excess payments through the use of cost containment techniques in their EAC programs. As a result, only about 7.9 percent, or $47 million of their expenditures are estimated as unnecessary.

Some states had developed cost containment measures for a number of drugs which resulted in lower payment limits. The most notable of these methods involved the use of state MAC systems for both name-brand and generic drugs (application of the Federal MAC approach to a large number of drugs statewide) and the use of direct purchase EAC data based on the direct manufacturers' prices for drugs generally purchased direct from manufacturers. We believe that the methods used by some states to contain drug reimbursement costs should be considered as potential "best practices" by HCFA, and used as guidance in improving the Federal criteria for controlling Medicaid reimbursement for prescription drugs.

In light of the significant program savings that can be realized by both the states and the Federal Government, we are recommending that the Administrator, HCFA, revise current policy and regulations to provide for better controls over Medicaid drug reimbursement. We are also recommending that the Administrator improve the information furnished State Medicaid agencies to assist them in evaluating their drug reimbursement limits. The actions proposed in this report (see page 23) are designed to restrict the use of AWP as an upper reimbursement limit and move states toward the use of drug pricing methods which will more closely approximate the prices pharmacies generally are paying for drugs.

The Administrator generally agreed with the findings in this report. She expressed concerns about some of our specific recommendations, but agreed that there is an opportunity to significantly reduce program expenditures in this area. The Administrator also stated that HCFA is not prepared to recommend any changes in the Federal regulations until the Secretary makes a decision regarding the findings of the special Task Force appointed to review the existing prescription drug regulations. While we recognize that the findings and recommendations of the Secretary's Task Force have not been finalized, we believe that HCFA can and should move forward at this time with certain actions which the Administrator acknowledges should be taken to provide greater assistance to the states in improving their controls over Medicaid drug reimbursement. (A more detailed discussion of HCFA's response and our comments are presented on page 24.)

DISCUSSION OF FINDINGS

MOST OF NATIONWIDE DRUG REIMBURSEMENT IS STILL BASED ON AWP

Although the purpose of the EAC regulations was to move states away from using published AWP as a basis for establishing drug reimbursement limits,

that goal is far from being achieved. Our fieldwork in six states and inquiries in 41 additional states indicated that the majority of EAC reimbursement limits are still being based on published AWP. On the basis of expenditure information provided by State Medicaid agencies during our inquiries, we estimated that the reimbursement limits for about 80 percent, or $1.3 billion of the $1.7 billion annual expenditures for Medicaid prescription drugs were based on AWP -- i.e., non-discounted list prices.

We found that 27 states still use AWP almost exclusively in establishing their EAC. The other 20 states based their EAC limits to a great extent on AWP; however, these states also used other techniques to establish more economical reimbursement limits for many drugs provided under their programs. The most common practices involved setting the EAC at the direct price offered by selected manufacturers and using state established MAC limits on multi-source drugs not covered by the Federal MAC program.

In the six states where we performed our fieldwork, most of the drug reimbursement was based on AWP upper limits. The following table summarizes the methodologies most commonly used by these states in establishing their upper reimbursement limits for our sample drugs.

Methodologies Used To Establish
Reimbursement Limits for Sample Drugs

	Ark.	Col.	Mass.	Mich.	N.Car.	Oreg.	Total
Average Wholesale Price	38	19	27	31	35	14	164
Direct Price		4	7			18	29
State MAC		11				4	15
Non-Covered Drugs		2	2	5	1		10
Totals	38	36	36	36	36	36	218

As can be seen, in 164 instances (75 percent) the upper limits for the drugs in our sample were based on AWP. In another 29 instances (13 percent) the limits were based on manufacturers' direct prices; while in 15 instances (7 percent) the limits were set using state MAC limits based on generic equivalent prices.

While the states sometimes obtain their AWP data from different sources, we found that the AWP figures used for specific drugs did not differ materially. Arkansas, Michigan and Oregon used the AWP published in the "American Druggist Bluebook", while Colorado and North Carolina used AWP data published in the "Drug Topics Redbook". Massachusetts used the AWP shown in a publication titled "Medi-Span, Inc. - Hospital Formulary Pricing Guide."

Three of the states visited -- Massachusetts, Oregon and Colorado -- establish EAC for certain drugs based on the manufacturers' direct prices. For example, Oregon establishes EAC at the manufacturer's direct price for drugs supplied by the following companies: Abbott Laboratories, Merck Sharp and Dohme, Parke Davis and Co., Pfizer Inc., J.B. Roerig and Co., E.R. Squibb and Sons, Inc., The Upjohn Company, Wyeth Laboratories, and Ross Laboratories. Both Colorado and Oregon had also established state MAC limits for many drugs not covered by the Federal MAC program. Colorado had established MAC limits for 176 drugs, and Oregon had established MAC limits for 150 drugs.

The table below compares the reimbursement limits established by the six states for 8 of our sample drugs.

Reimbursement Limits for Selected Drugs in Six Review States

Drugs	Ark.	Col.	Mass.	Mich.	N.Car.	Oreg.	Percentage By Which the High Exceeds the Low Price
Aldomet Tabs 250 mg 100's	$ 16.33	$ 15.85[d]	$ 12.68[g]	$ 15.85[d]	$ 16.34	$ 12.68[g]	29%
Artane Tabs 2 mg 100's	5.14	1.85[b]	5.15	5.14	5.14	3.85[b]	178%
Indocin Caps 25 mg 1000's	239.20	239.25	191.40[a]	239.30	246.80[c]	191.40[a]	29%
Motrin Tabs 400 mg 500's	108.25	72.00[b]	86.55[a]	108.30	111.90[c]	86.55[a]	55%
Periactin Tabs 4 mg 100's	15.78	5.95[b]	15.79	15.79	15.79	12.63[a]	165%
Thorazine Tabs 25 mg 100's	8.70	3.33[b]	8.70	8.70	8.10[e]	3.75[b]	161%
Vibra Tabs 100 mg 50's	67.41	53.94[b]	67.41	67.42	67.41	56.77[a]	25%
Vistaril Caps 50 mg 500's	149.80	74.75[b]	157.10[c]	143.10[f]	157.05[c]	126.15[a]	110%

Note: Unless otherwise noted the reimbursement limits shown above were based on the AWP for the drug product and package size indicated.

a/ The State established its reimbursement limit for this drug based on the manufacturer's published direct price.
b/ The State established a MAC limit for this drug based on the price of a generic equivalent drug.
c/ The State established its reimbursement limit for this drug based on the AWP for the 100 size package.
d/ The State established its reimbursement limit for this drug based on the AWP for the 1000 size package.
e/ The State established its reimbursement limit for this drug based on the AWP less 7 percent.
f/ The State had not changed its reimbursement limit to reflect the new AWP.
g/ The State established its reimbursement limit for this drug based on the manufacturer's published direct price for the 1000 size package.

As can be seen from our comparison, (1) AWP is the most frequently used reimbursement limit for these sample drugs, and (2) the drug reimbursement limits vary widely between the states using AWP and the states using cost containment methods. Some of the large variations can be explained by Massachusetts and Oregon having considered the direct purchase prices in establishing the EAC for the drug. The larger variations, however, resulted from Colorado and Oregon having established state MAC limits for the drugs.

In summary, several states have moved away from the sole use of AWP as their EAC and have established more economical reimbursement limits for some drugs. However, many states still use AWP almost exclusively in establishing their upper reimbursement limits and these states have apparently made no effort to establish drug ingredient cost limits that approximate the prices providers generally are paying for drugs.

We believe that the findings discussed in the remainder of this report clearly demonstrate that significant savings can be achieved if states will adopt procedures for establishing upper reimbursement limits that are more economical than the use of AWP.

PROVIDERS' DRUG INGREDIENT COSTS ARE MUCH LOWER THAN AWP

Although most of the program expenditures for prescription drugs are based on the use of published AWP as upper reimbursement limits, our review showed that pharmacies rarely purchased drugs at AWP. In fact, of the 3,469 drug purchases that we examined in the six states, only 14 purchases were made at AWP or greater. These 14 purchases were generally made only because of extenuating circumstances, such as special "fill-in" orders where discounts were not given because only one item was purchased. Most of the purchases -- 3,455 (99.6 percent) -- were made at prices averaging 15.93 percent below AWP. These drug purchases ranged from as little as 0.23 percent below AWP to as much as 41.78 percent below AWP. The range of discounts by state are shown in the following table.

	Range of Percentages Below AWP	
	Low	High
Arkansas	.45	40.54
Colorado	.83	37.36
Massachusetts	6.91	40.70
Michigan	1.61	41.78
North Carolina	1.43	39.18
Oregon	.23	37.36

It should be noted that only those purchase and trade discounts that could be identified to a specific drug purchase were considered. We were not able to readily determine other types of quantity, cumulative quantity, or year-end rebates and discounts which pharmacies may have received. Therefore, it is possible that the pharmacies' actual drug costs may have been lower than the discounted invoice prices. (The potential savings discussed on pages 15 and 16 may also be greater than the amounts we have estimated.)

Our examination of drug purchases showed that neither the location nor size of the towns in which the pharmacies were located, nor the types of ownership, affected the availability of discounts. Purchase discounts were available and were taken by pharmacies in all areas of the selected states, regardless of population, by both chain-owned and independently-owned pharmacies. Because of the limited number of pharmacies reviewed, no attempt was made to determine whether chain pharmacies received larger discounts than independent pharmacies. We noted, however, that the type of ownership made no difference with regard to the purchase and trade discounts received and reflected on the paid invoice records.

The pharmacies that we visited purchased drugs, either direct from pharmaceutical manufacturers or from pharmaceutical wholesalers. Of the 3,455 purchases made at prices below AWP, 1,127 (33 percent) were direct from manufacturers, and 2,328 (67 percent) were from wholesalers. Direct purchases resulted in greater discounts; such purchases were generally priced 17-24 percent below AWP, while wholesale purchases were priced from 10-15 percent below AWP.

PURCHASES DIRECT FROM MANUFACTURERS

Our review showed that drugs are purchased by pharmacies at lower prices when bought direct from manufacturers. Our examination of 1,127 direct purchase invoices showed that prices to pharmacies averaged 21.2 percent

below AWP; ranging from as little as 6.3 percent below AWP to as much as 41.8 percent below AWP. Of the 20 drugs in our sample that were available to pharmacies direct from the manufacturers, 10 were purchased direct over 50 percent of the time. For example, one of the selected drugs -- Motrin Tabs, 400 MG -- was purchased direct from the manufacturer by 82 of the 103 pharmacies which purchased the drug. The remaining 21 pharmacies purchased the drug from wholesalers. Another drug -- Ativan Tabs 1 MG -- was purchased direct from the manufacturer by 71 of the 98 pharmacies which purchased the drug. The remaining 27 pharmacies purchased the drug from wholesalers.

The following table shows some examples of drugs available direct from the manufacturers, and the percentage of discounts between AWP and the prices which we identified in our review as most frequently paid by pharmacies.

	AWP/Percentage Difference Between AWP/ Most Common or Median Price Paid					
Drug	Ark.	Col.	Mass.	Mich.	N.Car.	Oreg.
Clinoril Tabs (AWP)[1]	$ 43.66					
150 mg 100's	21.6%	21.6%	21.6%	21.6%	17.2%	21.6%
(Paid)	$ 34.23[2]	$ 34.23	$34.23	$ 34.23	$ 36.16	$ 34.23
Diabinese Tabs	$269.40					
250 mg 1000's	17.4%	16.2%	17.5%	17.5%	17.5%	17.5%
	$222.52[2]	$225.68	$222.38	$222.38	$222.38	$222.38
Hydropres 50	$ 16.87					
Tabs 100's	21.6%	21.6%	21.6%	21.6%	15.6%	21.6%
	$ 13.23[2]	$ 13.23	$ 13.23	$ 13.23	$ 14.24	$ 13.23
Inderal Tabs	$ 62.70					
10 mg 1000's	14.0%	14.0%	14.0%	13.3%	12.0%	12.6%
	$ 53.95[2]	$ 53.95	$ 53.93	$ 54.37	$ 55.21	$ 54.82
Minipress Caps	$ 87.10					
5 mg 250's	15.8%	15.8%	17.5%	10.0%	16.7%	15.9%
	$ 73.31[2]	$ 73.31	$ 71.89	$ 78.41	$ 72.53	$ 73.22

1/ The AWP prices for all 5 drugs represent the Bluebook AWP in effect during June 1983.

2/ Because our review in Arkansas was performed during a different period the price shown was not paid, but was computed based on percentage discounts determined during our Arkansas audit.

During our review in Arkansas, we noted about 34 high volume drug products which were available direct from 12 of the larger and better known pharmaceutical manufacturers. For the year ended June 30, 1982, program payments for each of these 34 drugs ranged from $51,000 to $595,000; payments for all 34 amounted to about $6 million or about 28 percent of the $21.4 million in total drug payments. If the State Medicaid agency had used published direct prices as the EAC upper limits (instead of AWP), for only these 34 drugs, we estimate that the savings would have been about $784,000 ($566,000 Federal share).

We found that some states have achieved cost savings by basing the EAC for some of their drugs on available direct manufacturers' prices, instead of AWP. For example, Oregon had established the EAC for 18 of our sample drugs at the available direct price; resulting in a substantially lower EAC for each than the states using AWP. (See discussion on page 7.)

Our review indicates that drugs which are available direct from the manufacturers represent a significant portion of total drug payments. Further, we found that most of the time pharmacies purchase such drugs direct from the manufacturers. The large volume of direct purchases is due, in our opinion, to the favorable price differential. Thus, we believe that, with minimal effort, substantial savings could be realized under the Medicaid drug program if State Medicaid agencies were required to use direct manufacturers' prices as their upper reimbursement limits for all drugs that are available direct from manufacturers.

PURCHASES FROM WHOLESALERS

The discounts below AWP or list price that were offered by drug wholesalers to pharmacies were not as large as those offered by drug manufacturers. However, many drugs are not sold direct and the purchases most frequently encountered during our review were from wholesalers. As mentioned earlier, of the 3,455 purchases examined which were made at prices below AWP, 2,328, or 67 percent, were purchased from pharmaceutical wholesalers. Discounts received by the purchasing pharmacies averaged about 13.6 percent below the AWP used by most State Medicaid agencies; ranging from as little as 0.23 percent below AWP to as much as 39.3 percent below AWP.

The following table shows five frequently prescribed drugs purchased from wholesalers and the percentages of discounts between AWP and the prices which we identified in our review as the most common or median price paid by pharmacies.

	AWP/Percentage Difference Between AWP/Most Common or Median Price Paid					
Drug	Ark.	Col.	Mass.	Mich.	N.Car.	Oreg.
Dalmane Caps (AWP)[1] 15 mg 500's	$ 77.55					
	10.7%[2]	13.3%	12.5%	16.4%	13.7%	16.7%
(Paid)	$ 69.25[2]	$ 67.22	$67.87	$ 64.81	$ 66.92	$ 64.63
Dyazide Caps 1000's	$126.70					
	13.0%[2]	15.0%	11.0%	11.2%	12.0%	10.8%
	$110.23[2]	$107.74	$112.70	$112.54	$111.54	112.98
Keflex Pulv. 250 mg 100's	$ 50.04					
	12.0%[2]	13.2%	12.0%	12.4%	12.0%	16.7%
	$ 44.04[2]	$ 43.43	$ 44.02	$ 43.86	$ 44.04	$ 41.70
Mellaril Tabs 10 mg 100's	$ 13.62					
	10.0%[2]	13.2%	11.0%	10.0%	12.0%	10.6%
	$ 12.26[2]	$ 11.82	$ 12.12	$ 12.26	$ 11.99	$ 12.18
Tagamet 300 mg 100's	$ 30.45					
	13.0%[2]	13.2%	11.2%	14.7%	12.0%	13.3%
	$ 26.49[2]	$ 26.42	$ 27.04	$ 25.96	$ 26.80	$ 26.40

The evidence disclosed during our review indicates that significant savings can be realized if State Medicaid agencies would base their EAC upper limits on the prices generally being paid by pharmacies for wholesale purchases rather than published AWPs. Such savings are particularly evident through the analyses of individual drugs. For example, in Arkansas about $358,000 was reimbursed to pharmacies for Dyazide. Our review has shown that a net savings of about $23,000, or 6.42 percent, 3/ would have been possible had the State Medicaid agency used -- as an upper limit -- an estimate of the price pharmacies generally paid for Dyazide, instead of using AWP. Likewise, about $762,000 was reimbursed to pharmacies for Tagamet. Our review showed that a net savings of about $80,900, or 10.62 percent, 3/ would have been possible for Tagamet, had the State agency used as its EAC a realistic estimate of the price generally paid for the drug by pharmacies.

1/ The AWP prices for all 5 drugs represent the Bluebook AWP in effect during June 1983.

2/ Because our review in Arkansas was performed during a different period the price shown was not paid, but was computed based on percentage discounts determined during our Arkansas audit.

3/ Net savings after considering the effect of the pharmacies' usual and customary charges on the calculation of drug payments. (See page 15 for discussion of UCC effect on drug payments.)

Payments for Tagamet in Arkansas equaled about 3.6 percent of the total Arkansas drug program. If this same percent of usage occurred nationwide, about $58 million would have been paid for Tagamet. The actual price paid for Tagamet in our selected states is about the same as in Arkansas. Therefore, a net savings of about $6 million may have been possible if all the State Medicaid agencies had used -- as an upper limit -- an estimate of the prices pharmacies generally paid for Tagamet, instead of using AWP.

SIGNIFICANT COST SAVINGS ARE POSSIBLE

During our pilot review in Arkansas, we made an extensive examination of the prices paid by pharmacies for our selected drugs. We found that 2,072 purchases were made at prices averaging 15.74 percent below AWP. Further review of the prices paid by pharmacies for these drugs in the five additional states disclosed an almost identical average discount of 15.96 percent below AWP. We believe that our review has amply demonstrated that the same or very similar discounts on drug ingredient costs are available and taken by pharmacies throughout the country. Therefore, an extrapolation of the percentage of savings in Arkansas to the nationwide total of Medicaid drug payments based on AWP should represent a reasonable estimate of the potential nationwide program savings.

PILOT REVIEW IN ARKANSAS

In Arkansas, our examination of 2,086 purchase invoices on the 38 sampled drugs at 60 pharmacies throughout the State showed that 2,072, or 99.3 percent of these purchases, were made at discounts ranging from as little as 0.5 percent below AWP to as much as 40.5 percent below AWP. The average purchase price was 15.74 percent below AWP.

Based on the prices obtained from pharmacy purchase invoices, we established price arrays for the most frequently purchased package sizes for each of the

selected drugs. (If one package size was not generally purchased more frequently than another then more than one price array was established). From these arrays we selected the most common price or median price that the pharmacies paid for the particular drug. These prices then served as the bases for our estimate of the effect of the State Medicaid agency's use of AWP as the upper limit for drug reimbursement.

Through the use of a computer application we recomputed the payments which would have been made, for the year ended June 30, 1982, had the State Medicaid agency used the prices which the 60 pharmacies generally paid for the sample drugs, instead of using the AWP payment methodology. The computer application was designed to utilize the State agency's existing drug reimbursement formula which was based on the Federal formula. All pertinent information included on the original paid claims was used, except that the drug prices generally paid by pharmacies, as determined in our review, were substituted for the State agency's AWP file.

The computer application showed that payments to the 60 pharmacies for the 38 drugs would have amounted to $720,985, instead of the $809,836 paid, had the State agency established its EAC upper limits for drug ingredient reimbursement at prices that were representative of the amounts which pharmacies actually paid for the drugs. Thus, for the year ended June 30, 1982, a savings of $88,851 (11 percent) would have been possible for the 38 selected drugs. Based on our extrapolation of this variance to the total Medicaid drug payments, we estimated that the potential annual program savings in Arkansas could amount to about $3.3 million ($2.4 million Federal share). (See OIG Report On Potential For Significant Cost Savings In Medicaid Prescription Drug Program, Arkansas Department of Human Services, Audit Control Number 06-40203, Issued December 16, 1983.)

Because drug sales are competitive, many pharmacies bill the program for less than AWP (for drug ingredient cost) plus the designated dispensing fee. Therefore, the Arkansas State agency's consideration of their drug providers' usual and customary charges (UCC) -- as required by the Federal reimbursement formula -- has served an important role in limiting drug payments. Although the pharmacies included in our review purchased drugs at discounts averaging 15.74 percent below AWP, our review showed that a lower 11 percent savings would have been possible. The difference between the average 15.74 percent discount and the 11 percent savings is attributable to the effect of UCC on the calculation of drug payments. For example, if the pharmacy's UCC was higher than drug ingredient cost plus dispensing fee, then our calculation received the full benefit of the potential savings. If, however, UCC was lower than drug cost plus dispensing fee, our calculation received only partial or none of the potential savings.

As long as UCC is used in the Medicaid reimbursement methodology, we believe that the competitive factor will help control the cost of prescription drugs. However, if Arkansas and all other states would base their EAC on the prices pharmacies generally pay for the drugs, substantial additional program savings could be realized. The scope of our review did not entail verification as to whether other states were considering pharmacies' UCC in their drug reimbursement systems. Therefore, if any states are not considering UCC, our estimate of the nationwide savings potential, as described below, will be conservative.

NATIONWIDE SAVINGS POSSIBLE

The use of AWP as an upper limit for Medicaid drug reimbursements is a nationwide problem which is resulting in significant unnecessary program

expenditures. In order to demonstrate the extent and significance of this problem, we reviewed drug purchases by pharmacies in five additional states -- Massachusetts, North Carolina, Michigan, Colorado and Oregon. In the additional states we examined 1,383 drug purchases in 48 participating pharmacies, and found that all of the purchases were made below AWP. These drug purchases were made at prices averaging 15.96 percent below AWP; very close to the average variance of 15.74 percent found in Arkansas.

The impact from the use of AWP on the Medicaid drug program has been substantial. The Medicaid drug program expenditures for the year ended December 31, 1982, totaled about $1.7 billion nationwide. Our inquiries in 47 states showed that about $1.3 billion, or about 80 percent of these expenditures were reimbursed under systems with AWP serving as the upper reimbursement limit. Of the $1.3 billion that was reimbursed using AWP, approximately $735 million (55 percent) was paid in 27 states using AWP almost exclusively in establishing their EAC. Based on our analysis in Arkansas, as described earlier, we believe that 11 percent, or about $81 million (Federal share $46 million) of these expenditures were unnecessary. The remaining 20 states had expenditures of about $590 million (45 percent) based on AWP; however, these states had already avoided sizeable excess payments through the use of other cost saving techniques in their EAC programs. (Examples are discussed on page 7.) As a result, only about 7.9 percent, or about $47 million (Federal share $26 million) of their expenditures were estimated as unnecessary.

In summary, we believe that as much as $128 million ($72 million Federal share) in Medicaid expenditures could be saved annually if program policy and regulations were revised so as to require states to abandon the AWP reimbursement methodology in favor of drug pricing systems which would more closely estimate the prices pharmacies generally pay for drugs. (See Schedule I)

DRUG PRICING ASSISTANCE PROVIDED BY HCFA CAN BE IMPROVED

HCFA has periodically supplied State Medicaid agencies with drug pricing data designed to assist them in evaluating their EAC limits. States receive the data from HCFA in a report titled "Price Information for Drug Products -- Invoice Level Prices." (The data has also been made available on machine readable magnetic tape.) The report shows percentile listings of invoice price statistics for a sample of frequently prescribed drugs in the largest selling package sizes. The pricing statistics are based on invoice prices received under contract from some 750 pharmacies located across the continental United States. The pricing data is gathered from small, medium and large pharmacies and is supposed to reflect the drug acquisition costs of those pharmacies. HCFA officials have surveyed the contract data and have contended that the 70th percentile of the pricing data (presented in the reports to the states) is a close approximation of what pharmacists are routinely paying for drug products. Thus, HCFA officials have suggested that the 70th percentile prices presented will suit the State Medicaid agencies' purpose for establishing EAC levels.

Based on our review of the HCFA pricing information for February 1983, we believe that the data supplied to the states has not contributed to solving the problem of excessive program payments for prescription drugs. The reports may have even been counterproductive since the amounts furnished have often been very similar to the AWP for individual drugs. This disparity, in our opinion, is a result of the method used by HCFA in determining the prices pharmacies pay for drugs. The statistics gathered by HCFA are based on

drug prices shown on invoices. These prices are generally list prices and do not reflect any purchase or trade discounts received when payments are made by the pharmacies.

The February 1983 HCFA pricing information contained data on 32 of our 36 selected drugs. However, the drug cost data which we obtained from pharmacies for 19 of the drugs was not comparable to the HCFA data due to price changes or differences in package size. Comparable data was available for the remaining 13 drugs.

Using the February 1983 HCFA pricing data, for the 13 drugs we compared the Blue Book AWP, the HCFA suggested 70th percentile price and the 70th percentile price obtained for the specific drugs during our review of pharmacy purchases. (From the prices obtained during our examination of pharmacy records, we established price arrays for the purchased package sizes. From these arrays, we selected the price at which or below which 70 percent of the purchases of the specific drug were made.) The results of our comparison are shown on the following page.

Comparison of the Bluebook AWP, the HCFA Suggested 70th Percentile Price, and the 70th Percentile Price per Audit

Drug	AWP	HCFA Suggested 70th Percentile	Percent Variance	70th Percentile Price Per Audit	Percent Variance
Aldactazide Tabs 100's	$ 23.75	$ 23.76	(.04)%	$ 21.71	8.59%
Artane Tabs 2 mg 100's	5.14	4.92	4.28%	4.34	15.56%
Darvocet N-100 500's	88.00	88.00	-0-	77.45	11.99%
Diabinese Tabs 250 mg 1000's	269.40	226.90	15.78%	226.91	15.77%
Dyazide Caps 1000's	126.70	126.80	(.08)%	112.82	10.96%
EES 400 Tabs 100's	21.95	19.56	10.89%	16.49	24.87%
Inderal Tabs 10 mg 1000's	62.70	61.20	2.39%	55.04	12.22%
Keflex Pulv 250 mg 100's	50.04	50.04	-0-	44.20	11.67%
Lasix Tabs 80 mg 50's	10.05	10.05	-0-	8.88	11.64%
Tagamet Tabs 300 mg 100's	30.45	30.45	-0-	27.09	11.03%
Vibra Tabs 100 mg 50's	67.41	57.00	15.44%	56.77	15.78%
Vistaril Caps 50 mg 100's	31.40	31.40	-0-	26.54	15.48%
Zyloprim Tabs 300 mg 100's	23.00	23.00	-0-	20.70	10.00%

Our comparison shows that the HCFA suggested 70th percentile price is not a close approximation of what pharmacies generally pay for drugs and, thus, would not appear to be of much value to the states in evaluating their EAC limits. For 8 of the 13 drugs (62 percent), the HCFA furnished 70th percentile price equaled or exceeded AWP. For the same 8 drugs, however, the 70th percentile of the purchase prices that we obtained from pharmacies ranged from 8.59 percent to 15.48 percent below AWP. In two other cases,

the HCFA furnished 70th percentile price was only 2.39 percent and 4.28 percent below AWP, while our audit 70th percentile price was 12.22 percent and 15.56 percent below AWP. In only 3 cases was the HCFA furnished price materially below AWP.

During our review, we noted that the drug price shown on the purchase invoice from a pharmaceutical wholesaler was generally the non-discounted published AWP. We also noted that the price shown on an invoice from the manufacturer was generally the published manufacturer's direct price. In the above table, the HCFA 70th percentile price for 8 drugs was equal to or greater than the AWP. In all 8 cases the drugs were purchased from wholesalers most of the time. On the other hand, the three drugs where the HCFA price was materially below AWP were frequently purchased direct from the manufacturers. Thus, it appears that the HCFA furnished 70th percentile price for drugs that are generally purchased from pharmaceutical wholesalers is not a close approximation of what pharmacists generally pay for drugs. To the contrary, the HCFA furnished price is more likely to be AWP itself. On the other hand, for drugs that are available direct from pharmaceutical manufacturers, the HCFA furnished 70th percentile price is closer to the prices pharmacies are paying direct to the manufacturers.

During our discussions with officials of the HCFA Pharmaceutical Reimbursement Section, who are responsible for issuing the drug pricing guidance to the states, we were informed that the pricing data is based on the prices shown on the pharmacies' invoices and do not reflect any discounts that are received when payments are made by the pharmacies. We believe that the way HCFA determines purchase prices is a major factor in why so many of the suggested 70th percentile prices equal or exceed AWP. Unless the purchase discounts and trade discounts received by pharmacies when payment is made are considered, the prices pharmacies generally are paying for drugs cannot be reasonably estimated.

Other prior studies have also raised questions about the adequacy of the drug pricing data furnished to the states by HCFA. A 1979 study 1/ sponsored by a grant from Roche Laboratories, which compared the Redbook AWP with the HCFA 70th percentile price for 222 drugs, reported that for over half (119) of the drugs the HCFA price was equal to the AWP. For another 32 drugs, the HCFA 70th percentile price exceeded the AWP, and for only about a third (71) of the drugs examined was the 70th percentile less than the AWP. In a report issued by the Comptroller General of the United States in the latter part of 1980, 2/ the General Accounting Office also concluded that the HCFA suggested "benchmark" prices, designed to help states establish their EAC limits, were most often near AWP.

STATES ARE INTERESTED IN POTENTIAL DRUG PROGRAM SAVINGS

Currently, state Medicaid agencies are facing more restrictive budgets than they have ever encountered before. Because of this, they are actively seeking cost containment measures in their Medicaid programs. At the time this report was being drafted, we noted that two states in Region VI were

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1/ "Federal Control of Pharmaceutical Costs, the MAC Experience," report prepared for Roche Laboratories Division of Hoffman La Roche, Inc. (May 1979), Jean Paul Gasnon and Raymond Jang, pp. 56-59.

2/ "Programs to Control Prescription Drug Costs Under Medicaid and Medicare Could Be Strengthened," HRD-81-36, December 31, 1980.

considering changes to their drug reimbursement systems in order to achieve program savings. We believe that other states will be interested in moving away from the use of AWP as an upper reimbursement limit for prescription drugs, as further information is disseminated regarding the potential for significant savings.

As discussed on page 14, in December 1983 the OIG issued an audit report pointing out potential annual savings of about $3.3 million ($2.4 million Federal share) in the Arkansas prescription drug program. Because of budget deficits, the Arkansas Human Services Department must reduce Medicaid expenditures by $6.6 million during the last 4½ months of fiscal year 1984. Along with implementation of other cost-cutting measures, the Director of the State Medicaid agency has advised the State Legislature that his agency will change its current system and base drug reimbursement on the actual costs paid by pharmacies rather than AWP. He further advised that this action, which should be done by the end of March 1984, would save an estimated $1 million during the remainder of the fiscal year. This action will be compatible with the findings and recommendations made in the Arkansas report.

The State of Texas, which has the fifth largest Medicaid drug program in the country, is also planning changes to its drug reimbursement system in order to achieve program savings. The Texas Department of Human Services' existing EAC provisions have recognized the difference between the cost of drugs purchased on a direct basis versus wholesale purchases. The State agency has achieved savings by limiting program reimbursement for drugs available from manufacturers to the manufacturers' direct prices. However, about two-thirds of the State's Medicaid drugs are purchased from wholesalers and the State agency uses AWP as the upper reimbursement limit for these drugs. State agency officials believe that further significant savings can be achieved if they eliminate the use of AWP as an upper reimbursement limit, and they are currently pursuing a more aggressive definition of EAC for drugs purchased from wholesalers.

On September 9, 1983, the Commissioner of the Texas Department of Human Resources submitted written comments to the six questions that are of specific interest to the Departmental Task Force established by the Secretary to review Federal reimbursement for prescription drugs. Among other comments, the Commissioner stated that new reimbursement policies should be developed that will move more toward "actual acquisition cost" without the associated administrative problems. In this regard, the Commissioner stated that his agency was (1) looking at policies to stress accurate reporting of direct drug cost information by drug manufacturers, and (2) examining a policy proposal to place a cap on reimbursement for drugs purchased wholesale. This cap would be based on wholesalers' actual drug costs plus a customary percentage mark up.

On February 22, members of our staff discussed the Texas State agency's plans for future drug reimbursement with the Director of the Medicaid Prescription Drug Program and his staff. We were told that the Texas Board of Human Resources has directed the State agency to explore alternative drug reimbursement policies. In this connection, the Program Director and his staff have decided upon a tentative plan of action which they believe will lead to the elimination of "redbook inflation" and allow the State to share in drug wholesale discounts. The Texas staff plans to obtain manufacturers' prices to wholesalers (wholesalers' drug costs) from manufacturers of drugs covered under the Texas program. The Program Director plans to perform surveys of selected drug purchases at a sufficient number of pharmacies to arrive at the customary mark up on wholesalers' drug costs. If the Texas staff is successful in their current effort, the State's EAC for drugs purchased from

wholesalers would be wholesalers' cost plus a reasonable mark up. Such a system would probably result in significant savings since it would eliminate "redbook inflation", as well as allow the Medicaid program to participate in wholesale discounts. The key to this system is collection of drug manufacturers' prices to wholesalers. The Program Director feels that the State agency can collect this data. However, the Director suggests that it would be more logical for the Federal Government (HCFA) to collect this data from one central point and make the data available to the states for their use in arriving at improved upper limits for drug reimbursement. We agree with this logic and believe that HCFA should explore this alternative. We believe that the Texas State agency's plans are compatible with the findings in this report.

CONCLUSIONS

Because HCFA believed that AWP was too high, a primary objective of the EAC requirement in the Federal regulations was to move the State Medicaid agencies away from using this source as the basis for establishing upper reimbursement limits. While some states have led the way in devising cost containment techniques for reimbursing their drug providers, overall, the EAC objective has not been met. We believe that the findings presented in this report demonstrate that the methods used nationwide in determining EAC have predominately resulted in drug reimbursement limits that are significantly higher than the prices pharmacies generally pay for their drugs.

We do not take issue with the basic reimbursement concept adopted by HCFA -- i.e., that the program should pay for no more than drug ingredient cost plus reasonable dispensing fees designed to cover the providers overhead and profits. However, pharmacies do not purchase drugs at the AWP published in the "Bluebook," "Redbook," or similar publications. Thus, AWP cannot be the best -- or even an adequate -- estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices.

The Secretary recently established a special Departmental Task Force to review Federal reimbursement for prescription drugs. We believe that our findings, which demonstrate the need for revision of the Medicaid policies and regulations, are pertinent to the Task Force's study. The revised regulations should eliminate the use of AWP and require State Medicaid agencies to aggressively pursue alternative methods for establishing upper reimbursement limits. The methods currently being used by some states to contain drug reimbursement costs demonstrate that drug pricing methods are available which will more closely approximate the prices pharmacies generally are paying for drugs. These "best practices" should be considered by HCFA in improving the Federal criteria for controlling Medicaid reimbursement for prescription drugs. HCFA should also improve the guidance furnished State Medicaid agencies to assist them in evaluating their drug reimbursement limits.

We believe that our estimated annual savings of $128 million ($72 million Federal share) will be achievable, once changes in program policy and regulations have been made by HCFA and State Medicaid agencies have had an opportunity to implement good systems for arriving at meaningful upper reimbursement limits for drug ingredient cost.

RECOMMENDATIONS

We recommend that the Administrator, HCFA,

1. Revise the existing drug reimbursement regulations by including more definitive criteria concerning the requirement for establishment of EAC. In this regard, we recommend that the regulations be revised to:

   a. Include language that will preclude the general use of AWP as the State agencies' "best estimate of prices providers generally are paying for drugs."

   b. Require that State Medicaid plans include descriptions of the methods being used to establish upper reimbursement limits for drug ingredient cost, and

   c. Require that the State Medicaid agencies provide assurances to HCFA that the methods used result in pricing estimates as close as feasible to the prices generally being paid by the providers.

2. Issue implementing instructions which will furnish guidance to the State agencies in establishing acceptable drug reimbursement limits. The guidelines furnished should include information on "best practices" used by some states to contain drug reimbursement.

3. Work with State agencies in developing alternative drug reimbursement methodologies which more closely approximate the prices pharmacies pay for drugs. In this regard, we suggest that HCFA assist the Texas State agency in its current efforts to arrive at reasonable payments for drugs (See pages 20 and 21). We believe that it may be feasible and more economical for HCFA to collect data on manufacturers' prices to wholesalers and furnish such data to all states. Also, HCFA should assist interested State agencies in efforts to determine a reasonable mark up on wholesalers' cost.

4. Review the current system for obtaining and furnishing invoice level drug pricing data to states for use in evaluating upper reimbursement limits. If a decision is made to continue supplying data of this nature to states, the Administrator should assure that the drug prices collected from pharmacies and provided to states reflect purchase and trade discounts received. Collection of manufacturers prices to wholesalers (wholesalers' cost) may result in data more useful to the States in arriving at economical reimbursement limits for drugs.

HCFA RESPONSE AND OIG COMMENTS

In a Memorandum dated May 22, 1984 (See Appendix), the Administrator generally agreed with the findings in this report. She expressed concerns about some of our specific recommendations, but agreed that there is an opportunity to significantly reduce program expenditures in this area. (The Administrator's primary concerns are addressed below.) The Administrator

also stated that HCFA is not prepared to recommend any changes in the Federal regulations until the Secretary makes a decision regarding the findings of the special Task Force appointed to review the existing prescription drug regulations. While we recognize that the findings and recommendations of the Secretary's Task Force have not been finalized, we believe that it is important to note that (1) the present regulations provide that EAC must be the State agency's best estimate of the price providers generally are paying for a drug, and (2) our report demonstrates on a nationwide basis that pharmacies are purchasing drugs at prices considerably below published AWP. Thus, AWP is not an adequate estimate of the prices providers generally are paying for drugs. We further believe that our findings are pertinent to the Task Force's study since they demonstrate that the existing regulations, which have been in effect since 1978, will need to be revised in order to restrict the use of AWP as an upper reimbursement limit. We also believe that HCFA officials can and should move forward at this time with certain actions which they acknowledge should be taken to provide greater assistance to the states in improving their controls over Medicaid drug reimbursement.

The Administrator felt that our first recommendation, regarding revision of the regulations to preclude the general use of AWP, is premature until such time that HCFA has developed alternative pricing mechanisms. She agreed, however, that action needs to be taken to provide greater assistance to the States in the determination of EAC. She advised that such assistance includes (1) exploring alternative data sources to assist states in determining acquisition costs, and (2) advising states of the problems of using AWP and suggesting alternatives to them. For example AWP might be reduced by a certain percentage to reflect quantity and trade discounts, not reflected in Red Book prices.

Our report describes some alternative pricing methodologies that are available and being used by some states as cost containment measures. Other alternatives should be explored, as the Administrator indicates will be done. However, it is doubtful that the regulations could ever be revised so as to prescribe a specific pricing mechanism. Rather, we believe that the regulations can be revised to include language that will preclude the general use of AWP as an upper limit for Medicaid reimbursement. We recognize that AWP may still be appropriate in those limited cases where drugs are infrequently used and no other pricing data is available. We see no reason why the regulations could not be revised as soon as possible to significantly restrict the use of AWP as an upper reimbursement limit and require states to initiate drug pricing methods which will more closely approximate the prices pharmacies generally are paying for drugs.

The Administrator did not fully agree that the revised regulations would need to require State plans to include descriptions of the pricing methods used and State agencies to provide assurances to HCFA that the methods used result in pricing estimates as close as feasible to the prices generally being paid by the providers. She stated that HCFA does require State plans to reflect MAC and EAC methodology. She added that requiring assurances from states appears redundant since each state is charged under the present regulations with the responsibility of determining its best estimate of the acquisition cost of each drug. We are concerned that State plans are not specific regarding the methodology used to arrive at EAC. In addition, assurances by State agencies have been found to be acceptable and useful in Medicaid reimbursement for other services (i.e., nursing home services). We believe that these requirements should be implemented because they would be beneficial to HCFA in developing an inventory of drug pricing methods being used and in evaluating the methods to determine those that are most effective in cost containment.

With regard to our second recommendation—that HCFA issue implementing instructions which will furnish guidance to the State agencies in establishing acceptable drug reimbursement limits—the Administrator felt that HCFA had furnished considerable guidance to the states on how to implement the EAC provisions. However, she agreed that there is a need for additional direction in this area and stated the HCFA will take steps to carry out the intention of this recommendation.

The Administrator concurred with the intent of our third recommendation concerning HCFA involvement in developing alternative drug reimbursement methodologies. However, she expressed some concerns about the possible outcome. The Administrator pointed out that any attempt to obtain actual drug product costs will be resented by the pharmaceutical industry. She also stated concern that any reduction in EAC screens by HCFA may well result in pressure by the pharmaceutical industry to increase state dispensing fees accordingly and the net result may be zero. While we can understand the basis for the Administrator's concerns, our report demonstrates that the Medicaid program is currently reimbursing pharmacies amounts for drug ingredient cost that are significantly in excess of the pharmacies' actual costs of the drug ingredients—which is contrary to the intent of the existing Federal regulations. Further, based on our review, we believe that the existing regulations on setting drug dispensing fees (42 CFR 447.333) provide for sufficient controls and latitude to enable the State agencies to ensure that they are paying reasonable dispensing fees.

The Administrator agreed with our final recommendation regarding needed improvements in the drug pricing data that HCFA supplies biannually to states. She stated that HCFA will explore ways to either refine the existing system or to develop alternative data bases to better assist states in their determination of EAC. The Administrator noted that such an effort might require additional resouces and the commitment of sizable funds.

¶ 34,158 PRRB DECISION—REASONABLE COST OF MANAGEMENT FEES—ADEQUATE RECORDKEEPING

PRRB Hearing Dec. No. 84-D147, July 16, 1984 (cost reporting periods ending Dec. 31, 1978, 1979, and 1980). *Northwest Community Hospital (Des Moines, Iowa) v. Blue Cross and Blue Shield Association/Blue Cross of Iowa.*

Provider reimbursement—Cost related to patient care—Reasonable cost of management fees—Prudent buyer concept—Adequate recordkeeping.—The regulations require that a provider maintain auditable financial and statistical records to support costs claimed, including those incurred under management contracts. In addition, prudent buyer considerations require that the provider demonstrate that it sought the most cost-effective means of obtaining necessary management services. The intermediary correctly determined that the costs of a management contract negotiated by a hospital with a corporation that had previously managed the hospital during a receivership period were unreasonable, according to a comparative analysis indicating that the hospital's administrative costs were substantially out of line with those incurred by similar facilities.

The hospital had notice of the intermediary's componentization methodology for auditing management fees prior to incurring the costs at issue and was given ample opportunity to comply with the intermediary's request for documentation of services performed under the contract. The provider did not solicit bids or otherwise search the marketplace for comparable services and did not supply adequate documentation to support the reasonableness of the management fees incurred or its contention that it sustained overall cost savings in spite of its higher administrative and general costs. *Back references:* ¶ 5995B, 6420.59.

Issue

Whether management fees paid by the provider are reasonable?

Summary of Facts

The provider is a general, acute-care hospital.